K003317

NOV 21 2000

SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Trade Name: **RENEW® LS-1**
Common Name: **Tooth shade resin (composite restorative) material**
Classification Name: **Tooth Shade Resin Material, Class II**
21 CFR 872.3690

Description of Applicant Device:
RENEW® LS-1 is a packable, low shrink/low stress universal hybrid composite.

Intended Uses of Applicant Device:
Intended to be used primarily as a universal (anterior and posterior) dental restorative material to replace missing tooth structure as in:

1 Class I and II restorations.
2 Core build-ups,
3 Class III, IV, and V restorations with a microfill composite, where maximum strength and polishability is desired.

Predicate Device:
K 982729 RENEW®

Scientific Concepts and Significant Performance Characteristics:

	RENEW® LS-1	RENEW®
INTENDED USE:	Tooth shade resin composite indicated for all types of restorations.	Tooth shade resin composite indicated for all types of restorations.
PRODUCT DESCRIPTION:	• Universal (anterior and posterior) • Light-Cured • Hybrid composite • Radiopaque • Single paste	• Universal (anterior and posterior) • Light-Cured • Hybrid composite • Radiopaque • Single paste
CHEMICAL COMPONENT:	• Methacrylate resin chemistry with highly filled inorganic glass filler • Non-toxic	• Methacrylate resin chemistry with highly filled inorganic glass filler • Non-toxic

510(k) SUMMARY, continued

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Side-by-side comparisons of RENEW® LS-1 to the predicate device RENEW® clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

Comparative bench testing was conducted for RENEW® LS-1 and RENEW®. Review of the testing performed and its results may be found in Section 3, page 9. Based on the results of the bench testing it was concluded that RENEW® LS-1 performs as well as the predicate device, RENEW®, and therefore has proven its safety and efficacy.

Cyndy Oris
Manager, Regulatory Affairs
1-800-BIS-DENT or 847-534-6146
Fax: 847-534-6396

October 20, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Ms. Cyndy Oris
Regulatory Affairs Manager
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K003317
Trade Name: Renew® LS-1
Regulatory Class: II
Product Code: EBF
Dated: October 20, 2000
Received: October 24, 2000

Dear Ms. Oris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not Applicable

Device Name: RENEW® LS-1

Indications for Use:

RENEW® LS-1 is a single-paste, packable, low shrink/low stress universal hybrid composite for

1. Class I and II restorations.
2. Core Build-ups.
3. Class III, IV and V restorations with a microfill, where maximum strength and polishability is desired.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003317